HealthTech Report

Understanding production capacity of neonatal resuscitator manufacturers

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Introduction

Birth asphyxia, defined as the failure of the newborn to establish breathing immediately after birth, kills 814,000 newborns every year and accounts for almost a quarter of all newborn deaths.[1] More than 98 percent of these deaths occur in low- and middle-income countries (LMICs). Sixty million home- or community-based births happen every year; but most birth attendants do not have access to any resuscitation resources.[2]

In order to address this issue, Helping Babies Breathe (HBB)—a Global Development Alliance funded by the United States Agency for International Development—initiated an effort in 2010 to increase neonatal survival by offering evidence-based educational programs and high-quality, affordable neonatal resuscitation devices to skilled birth attendants in developing countries. In 2012, neonatal resuscitation devices were identified as 1 of 13 lifesaving commodities selected by the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) as part of the Every Woman Every Child movement with the overall goal to increase access to these 13 lifesaving commodities in 50 of the world's poorest countries.

In conjunction with these efforts, PATH has estimated the total market size for reusable neonatal resuscitation commodities that would be needed to effectively provide neonatal resuscitation in eight UNCoLSC pathfinder countries.[i] This estimate was based on a model framework that PATH developed through consultations with global experts and visits to health care facilities and stakeholders in Tanzania and Uganda. This model projects that nearly 400,000 units of reusable bag-and-mask resuscitators and nearly 400,000 units of reusable suction bulbs would be required for the eight UNCoLSC pathfinder countries (report available at: http://www.path.org/publications/detail.php?i=2408).[3]

Objective

As a follow-on activity to the market size estimate, PATH surveyed manufacturers of neonatal, self-inflating bag-and-mask resuscitators. We focused on neonatal, self-inflating bag-and-mask resuscitators in this survey because there has been a question among stakeholders about the need to seek additional manufacturers that can provide high-quality neonatal resuscitators at an affordable price to LMICs as the demand for this commodity has been growing.

The primary objectives of this survey were to (1) identify existing capacity of manufacturers to produce neonatal resuscitators and (2) assess their level of interest in being involved in HBB efforts. The survey asked manufacturers if they have neonatal resuscitators that meet the following clinical purpose (see Box 1) as described in the World Health Organization (WHO) draft "Technical Specifications for 13 Medical Devices on UN Life-Saving Commodities."[4] The survey then asked whether their resuscitators are reusable, and if so, how they can be cleaned for reuse.

Box 1. Clinical Purpose: Self-inflating resuscitator (bag and mask) having a bag size between 220 ml–400 ml and two masks, size # 1 for term babies and # 0 for preterm and low-birth-weight babies, with a pressure-release valve (pop-off valve) when pressure exceeds 40 +/- 5 cm H2O.

[i] Democratic Republic of the Congo [DRC], Ethiopia, Malawi, Nigeria, Senegal, Sierra Leone, Tanzania, and Uganda.

The draft WHO Technical Specifications categorizes neonatal resuscitators into "anesthetic and respiratory devices, electro mechanical medical devices, and single-use devices," using Global Medical Device Nomenclature codes. The Technical Specifications also state that resuscitators can be totally disassembled and are easy to clean and disinfect. Medical devices, regardless of whether they are labeled single use or reusable might be able to be cleaned and reused in low-resource settings for cost savings. This reality might be reflected in the draft Technical Specifications that categorizes neonatal resuscitators as single-use devices yet requires them to be cleanable.

However, medical devices that are registered and labeled as single-use devices by regulatory authorities should not be used as reusable devices, and manufacturers do not recommend cleaning and reusing single-use medical devices. For this reason, we inquired whether neonatal resuscitators are cleanable only if manufacturers answered that their resuscitators were reusable.

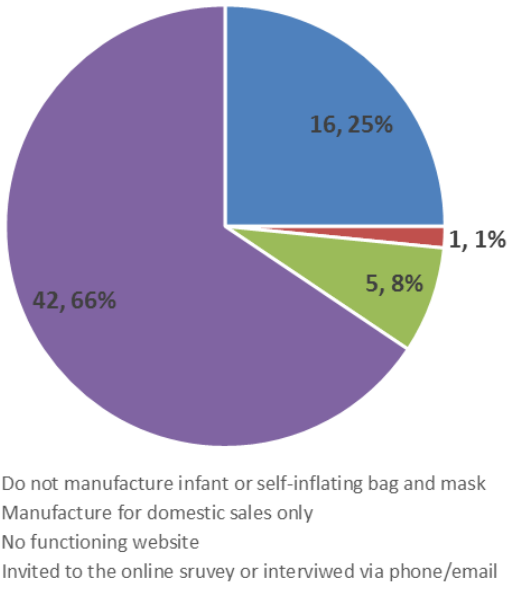
Methodology

We initially identified 64 suppliers of neonatal resuscitators from two sources: 1) the global inventory of neonatal resuscitators that PATH previously published[5] and 2) the list of suppliers that the United Nations Children's Fund (UNICEF) Supply Division used for its market and supply survey for neonatal resuscitators.[6, ii]

Out of 64 suppliers, we eliminated 22 companies that: 1) do not manufacture neonatal or self-inflating bag and masks; 2) manufacture neonatal resuscitators only for domestic sales; or 3) do not have a functioning website, which, therefore, made it difficult to obtain valid contact information (see Graph 1).

We subsequently invited the remaining 42 manufactures to an online survey site and asked them to complete a structured questionnaire. We subsequently followed up at least three times with manufacturers and encouraged them to visit the online survey site. Out of 42 manufacturers, 9 manufacturers visited the online survey site, and 5 manufacturers eventually completed the survey (refer to Appendix 1 for a list of manufacturers). In addition, we directly contacted two large manufacturers of neonatal resuscitators, Laerdal Medical AS and Ambu, who are known to supply neonatal resuscitators to LMICs. Of the seven manufacturers we surveyed, three are located in Europe, two are located in North America, and the remaining two are located in India. The following sections summarize the information that we obtained from these seven manufacturers.

Graph 1. Breakdown of manufacturers



[ii] PATH would like to thank the UNICEF Supply Division for sharing their list of suppliers.

Results

1. Neonatal resuscitators manufactured

All seven manufacturers responded that they have a neonatal resuscitation device(s) that meets the aforementioned clinical purpose that WHO describes in its Technical Specification for 13 Medical Devices on UN Life-Saving Commodities.[4]

Out of seven manufacturers who completed the online survey or were interviewed, three manufacturers have neonatal resuscitators for single use only while the remaining four manufacturers have reusable neonatal resuscitators. The four manufacturers that have reusable neonatal resuscitators stated the masks of their resuscitators are made from silicone and may be cleaned using an autoclave.

2. Manufacturing capacity

PATH estimated that the total market size for reusable bag-and-mask neonatal resuscitators for all eight UNCoLSC Pathfinder countries would be nearly 400,000 units. This estimate is based on the number of health care facilities in each UNCoLSC pathfinder country and the number of neonatal resuscitators needed at each facility. The market size estimates are for the initial stocking quantity. The frequency of repurchases is not forecasted.

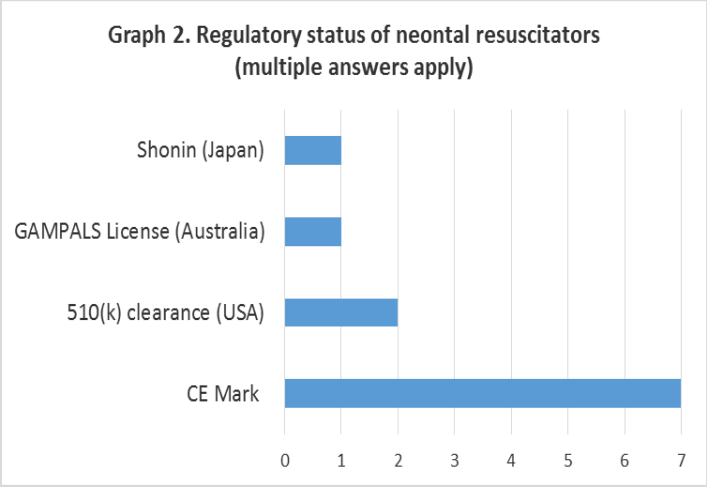
HBB's 2013 annual report states that 120,000 resuscitators were provided under its auspices to LMICs over the past ten years.[7] Although the UNICEF Supply Division and United Nations Population Fund (UNFPA) also procured neonatal resuscitators for distribution and use in LMICs, at present there appears to be a significant gap between the estimated market size and the quantities procured. Nevertheless, demand is expected to grow to the level of the estimate in the future as HBB's efforts continue and as health systems in LMICs continue to be strengthened. This is why there initially was a concern among stakeholders that manufacturers might not be able to meet the future demand.

Four of the seven manufacturers provided their current annual production capacity, which ranged from 12,000 units to more than 1,000,000 units. Three other manufacturers responded that they adjust their production quantity based on delivery schedules or market requirements. Six out of the seven manufacturers responded independently that they currently have adequate manufacturing capacity or will be able to increase their existing manufacturing capacity to produce 400,000 neonatal resuscitators annually. The current production quantity of reusable neonatal resuscitators is smaller than 400,000 units, reflecting the existing sales volume; however, their responses demonstrates that they have capacity to increase the production quantity to meet the future market demand.

We were initially concerned that the estimated total market size of 400,000 units for the eight UNCoLSC Pathfinder countries might be too small for some manufacturers to be interested in providing their products to LMICs. However, no manufacturers indicated that the estimated market size of 400,000 neonatal resuscitators would be too small for them to be interested since the current annual production capacity of the four manufacturers who responded is smaller than this number.

3. Regulatory status and export market

All seven manufacturers have the CE Mark for their neonatal resuscitators. Two manufacturers have United States Food and Drug Administration 510(k) clearance to sell their devices in the United States (Graph 2).



In addition, these seven manufacturers all sell their devices to various countries, including African countries, mainly through distributors and procurement agencies. Only one company answered that they sell their device primarily to Europe and the United States.

4. Interest of manufacturers in the HBB effort and challenges for them to work with LMICs

All manufacturers (with the exception of one who has already been an active partner to the HBB effort) expressed interest in becoming involved in HBB activities but stated that before doing so they would like to have more information. The one manufacturer who has already been working with HBB to supply products to LMICs mentioned that it was difficult to sell neonatal resuscitators to those countries due to their lack of transparency in procurement and logistics. The issues raised by this manufacturer are consistent with the ones that PATH's key informant interviews had previously identified. In 2011, PATH conducted interviews with ten experts who were familiar with implementation of HBB. These interviews identified procurement and logistics issues such as delays in customs clearance.[8]

An additional challenge had been that neonatal resuscitators are not included on national essential medicine/device lists of many countries. Some experts at the country level do not have the latest information about neonatal resuscitators despite the fact that the HBB has made significant progress in this regard. As procurements of neonatal resuscitators shifts from implementing partners to ministries of health in the future, this lack of awareness about high-quality neonatal resuscitators could lead to difficulty in sustaining the current level of demand or might even result in reduced demand for high-quality neonatal resuscitators. When the demand or order quantity becomes too small, it will be difficult for manufacturers to justify the investment that they must make in order to enter the market, including:

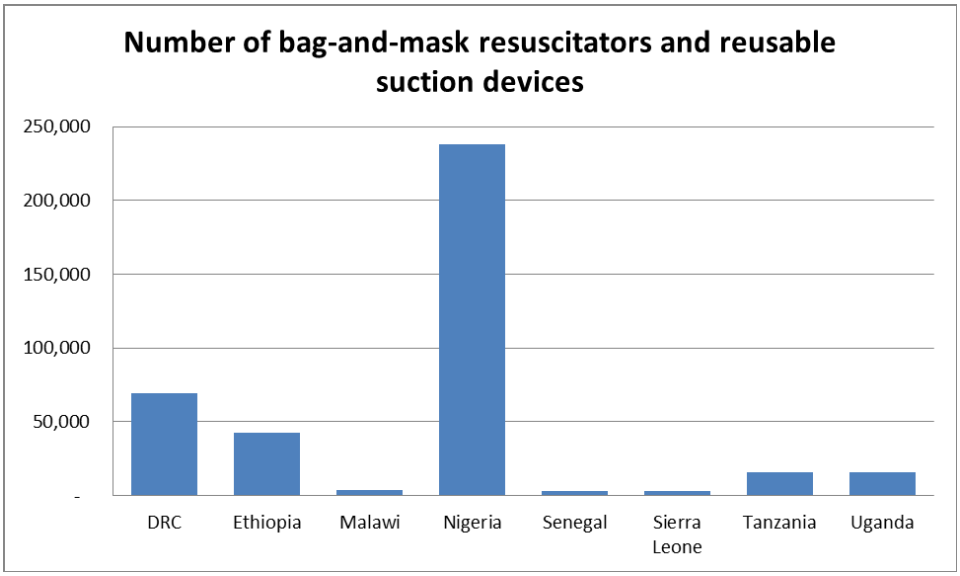
- Identifying and managing a local agent who can participate in government procurement tenders, distribute devices, and provide maintenance/repair as needed.
- Obtaining necessary regulatory approval/permits to import neonatal resuscitators.

5. Result summary

This survey has confirmed that insufficient capacity will not be a significant concern. All the manufacturers responded that they already have adequate manufacturing capacity or will be able to expand their current manufacturing capacity to produce 400,000 units of neonatal resuscitators. Although 400,000 units is the estimated market size for the eight UNCoLSC pathfinder countries, meeting the expected global demand will not be a concern for them in the foreseeable future for the following reasons:

- Of the eight countries, Nigeria has the largest market size, which is estimated to be 240,000. This is more than 60 percent of the total estimated market size for all eight of the countries, and it is more than three times larger than that of the second-largest country, the Democratic Republic of the Congo (DRC). The market size of each of the remaining six countries is less than 50,000 (see Graph 3 below) which is similar to the market size of most sub-Saharan African countries.
- As we noted in our previous report estimating market size, our market size estimates are for the initial stocking decision; the frequency of repurchases has not been forecasted and is not included in our estimates. In reality, it is unlikely that countries or implementing partners will purchase all of the required neonatal resuscitators at one time.

Graph 3: Estimated number of bag-and-mask resuscitators and suction bulbs



Estimates are for each commodity separately (e.g., in Nigeria 238K bag-and-mask resuscitators and 238K suction bulbs are needed).

In addition, this market survey has confirmed that the seven manufacturers are currently exporting to other countries. They expressed interest in learning more about HBB's efforts, since this could expand their market potential. One manufacturer, however, who already has experience in shipping neonatal resuscitators stated that it has been difficult to deal with some LMICs' non-transparent procurement and logistics practices. Furthermore, the absence of neonatal resuscitation devices on national essential medicine/device lists in many countries and the lack of understanding of in-country experts concerning the latest neonatal resuscitators will result in lower demand per country.

Going forward

This manufacturer survey has demonstrated that there are manufacturers who are interested in HBB efforts. All manufacturers stated that their neonatal resuscitators have the CE Mark, which is a good indicator of the quality of their devices. In regard to potential future activities, bench testing could be performed on some of the neonatal resuscitators to prove that the devices clearly meet the clinical purpose—the key aspect of the WHO draft Technical Specifications. Bench testing will be able to show that reusable neonatal resuscitators are indeed cleanable using the methods that are specified by manufacturers. In addition, although single-use devices are not designed for cleaning and reuse, they could be tested for cleanability with a variety of cleaning methods, considering the context for low-resource settings. The information obtained through bench testing could then be conveyed to manufacturers for consideration for relabeling.

This manufacturer survey combined with PATH's previous key informant interviews has highlighted the difficulty that manufacturers face in entering LMICs due to LMICs' lack of transparency in their procurement and logistic systems. Therefore, future efforts should focus on reducing market entry barriers to facilitate introduction of high-quality neonatal resuscitators. Reducing market entry barriers will also lower market entry costs for manufacturers, which in turn will likely lead to lower product pricing.

One might suggest developing a new mechanism to aggregate demand among multiple countries (pooled procurement) in order to reduce barriers to market entry. However, we would rather recommend using "existing" bulk procurement agencies and organizations such as UNICEF and UNFPA. They have already been procuring and distributing neonatal resuscitators to LMICs. By working as an intermediary between LMICs and manufacturers, these organizations have helped manufacturers to reduce costs that they would otherwise have incurred when opening each market on their own. We should expand on this effort and explore whether other international bulk procurers (e.g., Missionpharma, IDA Foundation, IMREF, I-Solution, etc.) could procure neonatal resuscitators for low-resource settings at an affordable price.

At the same time, efforts to strengthen capacity at the country level should be undertaken in the areas of: 1) raising awareness about and generating demand for high-quality neonatal resuscitators; 2) planning for procurement; 3) forecasting; and 4) supply chain management, including importation, storage, and in-country distribution.

PATH's procurement group is currently tasked with providing technical assistance to strengthen procurement capacity in Uganda, Tanzania, Malawi, and Ethiopia. PATH's technical assistance will include: 1) raising understanding and creating capacity around quantification; 2) developing procurement plans, specifications, and quality assurance mechanisms; and 3) understanding where and how to procure high-quality devices. Depending on the availability of additional funding, this technical assistance could be expanded to other LMICs as well.

Capacity development for LMICs, combined with leveraging existing distribution channels of international procurement agencies, will help to increase the availability of neonatal resuscitation devices in LMICs.

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[7] Helping Babies Breathe (HBB). *Status Report November 2013*. HBB; 2013. Available at: http://www.healthynewbornnetwork.org/sites/default/files/resources/HBB%20Annual%20report%2021%20Nov%202013%20Final_0.pdf.

[8] PATH. *HealthTech Report: Procurement and Logistics Issues Related to the Implementation of Helping Babies Breathe.* Seattle, Washington: PATH; 2011.

Appendix 1: List of manufacturers which responded to the online survey

- Allied Healthcare Product Inc.
- Ambu A/S
- BLS Systems Ltd.
- GPC Medical Limited
- Laerdal Medical A/S
- *Two (2) additional companies completed the survey. These company's names have been kept confidential upon their request.*